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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Chapter I

[EPA-HQ-OPPT-2018-0682; FRL-9988-56]

Asbestos; TSCA Section 21 Petition; Reasons for Agency Response

AGENCY: Environmental Protection Agency (EPA).

ACTION: Petition; reasons for Agency response.

SUMMARY: This document provides the reasons for EPA's response to a September 27, 2018, petition it received under the Toxic Substances Control Act (TSCA) from the following organizations: Asbestos Disease Awareness Organization, American Public Health Association, Center for Environmental Health, Environmental Working Group, Environmental Health Strategy Center, and Safer Chemicals Healthy Families ("petitioners"). Generally, the petitioners requested that EPA make multiple amendments to the Chemical Data Reporting (CDR) rule under TSCA by January 1, 2019, in order to increase the reporting of asbestos. After careful consideration, EPA denied the petition for the reasons discussed in this document.

FOR FURTHER INFORMATION CONTACT: For technical information contact: Tyler Lloyd, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., N.W., Washington, DC 20460-0001; telephone number: (202) 564-4016; email address: lloyd.tyler@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: [HYPERLINK "mailto:TSCA-Hotline@epa.gov"].

SUPPLEMENTARY INFORMATION:

18T-0312

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. This action may, however, be of particular interest to those persons who manufacture or process or may manufacture (which includes import) or process the chemical asbestos (CAS No. 1332-21-4). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. How can I access information about this petition?

The docket for this TSCA section 21 petition, identified by docket identification (ID) number EPA-HQ-OPPT-2018-0682, is available at https://www.regulations.gov or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at https://www.epa.gov/dockets.

II. TSCA Section 21

A. What is a TSCA section 21 petition?

Under TSCA section 21 (15 U.S.C. 2620), any person can petition EPA to initiate a rulemaking proceeding for the issuance, amendment, or repeal of a rule under TSCA sections 4,

6, or 8, or an order under TSCA sections 4, 5(e), or (f). Ex. 5 Deliberative Process (DP)

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If EPA grants the petition,

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the Agency must promptly commence an appropriate proceeding. If EPA denies the petition, the Agency must publish its reasons for the denial in the **Federal Register**. A petitioner may commence a civil action in a U.S. district court to compel initiation of the requested rulemaking proceeding either within 60 days of either a denial or, if EPA does not issue a decision, within 60 days of the expiration of the 90-day period.

B. What criteria apply to a decision on a TSCA section 21 petition?

TSCA section 21(b)(1) requires that the petition "set forth the facts which it is claimed establish that it is necessary to issue, amend or repeal a rule." 15 U.S.C. 2620(b)(1).

TSCA section 8(a)(1) authorizes the EPA Administrator to promulgate rules under which manufacturers (including importers) and processors of chemical substances must maintain such records and submit such information as the EPA Administrator may reasonably require (15 U.S.C. 2607). TSCA section 8(a)(2) outlines the information that the EPA Administrator may require under TSCA section 8(a)(1), insofar as it is known to the person making the report or insofar as reasonably ascertainable. Under TSCA section 8(a), EPA has promulgated several data collection rules, including the Chemical Data Reporting (CDR) rule at 40 CFR part 711.

III. Summary of the TSCA Section 21 Petition

A. What action was requested?

On September 27, 2018, the Asbestos Disease Awareness Organization, American Public Health Association, Center for Environmental Health, Environmental Working Group, Environmental Health Strategy Center, and Safer Chemicals Healthy Families (petitioners) petitioned EPA to amend the CDR rule under TSCA section 8(a), within 90 days of the petition being filed, in order to increase the reporting of asbestos under the CDR rule (Ref. 1).

The petitioners requested the following specific amendments to the existing CDR rule in order to collect information for the ongoing asbestos risk evaluation being conducted under TSCA section 6(b), which is required to be completed by December 22, 2019, and, if necessary, any subsequent risk management decisions under TSCA section 6(a):

- · Amend the CDR rule to require immediate submission, "from January 1, 2019, to April 31, 2019," of reports on asbestos for the 2016 reporting cycle (note: the petitioners incorrectly stated that there are 31 days in April. EPA has corrected this error throughout the remainder of this notice);
- · Amend the naturally occurring chemical substance exemption at 40 CFR 711.6(a)(3) to make the exemption inapplicable to asbestos;
- · Amend the articles exemption at 40 CFR 711.10(b) to require reporting pursuant to the CDR rule for all imported articles in which asbestos is present at detectable levels;
- · Amend the CDR rule to exclude asbestos from the exemption at 40 CFR 711.10(c) to require the reporting of asbestos as a byproduct or impurity;
- Amend the reporting threshold for CDR at 40 CFR 711.8(b) to set a reporting threshold of 10 pounds for asbestos; and
- · Amend 40 CFR 711.8 to add processors of asbestos and asbestos-containing articles as persons required to report under the CDR rule.

In addition to these amendments to the CDR rule, the petitioners requested that EPA "commit to making all reports submitted on asbestos publicly available notwithstanding any claims that these reports contain Confidential Business Information (CBI)" (Ref. 1). To disclose CBI reported under the CDR rule, the petitioners requested that EPA use its authority under TSCA section 14(d)(3) or 14(d)(7).

After submitting their petition on September 27, 2018, petitioners followed up with a subsequent email to Jeff Morris, Director of EPA's Office of Pollution Prevention and Toxics, on November 29, 2018, requesting to "incorporate in the petition by reference all the materials in EPA-HQ-OPPT-2016-0736, the docket for the TSCA Review and Risk Evaluation for asbestos" (Ref. 2). EPA has discretion (but not an obligation) to consider this type of request in this subsequent email when evaluating a petition submitted under TSCA section 21. In cases where the petitioners themselves attempt to enlarge the scope of materials under review while EPA's petition review is pending, EPA exercises its discretion to consider or not consider the additional material based on whether the material was submitted early enough in EPA's petition review process to allow adequate evaluation of the additional materials prior to the petition response deadline and the relation of the late materials to materials already submitted. In this instance, and as a threshold matter, EPA believes the petitioners have to set forth the facts contained in all those docket materials that they claim establish that it is necessary for EPA to amend the CDR rule in the manner requested. Indeed, they have made no showing at all in this regard. Thus, EPA believes that petitioners' attempt to supplement the petition record in this way does not fulfill the requirements of TSCA section 21(b)(1). Furthermore, EPA believes that through its evaluation of the petition, it already has, in fact, made use of the information in the docket for the TSCA Review and Risk Evaluation for asbestos, because, as discussed in Unit IV.A.i., that information informs much of EPA's understanding of the current uses of asbestos.

B. What support do the petitioners offer?

The petitioners state that TSCA section 8(a)(1) gives EPA broad authority to require manufacturers and processors of chemical substances to submit such reports as the "Administrator may reasonably require." The CDR rule, which is one of several reporting rules

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promulgated under TSCA section 8, requires manufacturers (including importers) to provide EPA with information on the production and use of chemicals in commerce, generally 25,000 pounds or more of a chemical substance at any single site, with a reduced reporting threshold (2,500 pounds) applying to chemical substances subject to certain TSCA actions, including, as applicable here, TSCA section 6. As the petitioners state, "the CDR rule is EPA's primary tool under TSCA for obtaining basic information on the manufacture, importation, and use of chemicals and the nature and extent of exposure to these substances" (Ref 1).

While asbestos is already required to be reported under the CDR rule by manufacturers (including importers) meeting certain criteria, the petitioners request amendments to the CDR rule that they contend will increase the reporting of asbestos. Petitioners contend that these amendments could provide EPA with "the comprehensive information on asbestos importation and use it needs for its ongoing risk evaluation" (Ref. 1). The petitioners claim that "the [CDR] rule has played no role in informing EPA about asbestos uses that could be addressed in the Agency's TSCA risk evaluation" (Ref. 1). Petitioners add that their amendments would "maximize EPA's ability to use the information reported to conduct the ongoing risk evaluation and the subsequent risk management rulemaking under TSCA section 6(a)."

In their request, the petitioners state that "asbestos is among the most dangerous chemicals ever produced, with expert bodies agreeing that there is no safe level of exposure." The petitioners cite research finding dangers from asbestos and provide a review of asbestos assessments and regulations under TSCA. In their petition, they state that in 1989, EPA determined that "nearly all uses of asbestos presented an 'unreasonable risk of injury' under section 6 of TSCA" and assert that "the basis for this conclusion is even more compelling today" (Ref. 1).

The petitioners state their belief that EPA "lacks the basic information required for a complete and informed risk evaluation that assures that unsafe asbestos uses are removed from commerce" (Ref. 1). To support their assertion, the petitioners point to EPA's asbestos Problem Formulation (83 FR 26998, June 11, 2018) (FRL-9978–40), which, they say, "attempts to identify the asbestos uses that EPA will address in its risk evaluation but its description of these uses is limited, vague and incomplete." Moreover, the petitioners cite language in the Problem Formulation that states that "the import volume of products containing asbestos is not known" (Ref 1).

IV. Background Considerations

A. Review of EPA actions, activities, and regulations

To understand EPA's reasons for denying the petitioners' requests, it is important to first review the details of EPA's ongoing risk evaluation of asbestos, the CDR rule, exemptions under the CDR rule, and past reporting of asbestos under the CDR rule, which are explained in the following sections.

i. Risk evaluation of asbestos. On June 22, 2016, Congress passed the Frank R.

Lautenberg Chemical Safety for the 21st Century Act (P.L. 114-182), which amended TSCA (15 U.S.C. 2601 et seq.). The new law includes statutory requirements related to the risk evaluations of conditions of use for existing chemicals. On December 19, 2016, in the Federal Register, EPA designated asbestos as one of the first 10 chemical substances subject to the Agency's initial chemical risk evaluations (81 FR 91927) (FRL-9956-47) pursuant to TSCA section 6(b)(2)(A) (15 U.S.C. 2605(b)(2)(A)), which required EPA to identify the first 10 chemicals to be evaluated no later than 180 days after the date of enactment of the Act.

EPA is currently evaluating the risks of asbestos under its conditions of use, pursuant to

TSCA section 6(b)(4)(A). Through scoping and subsequent research for the asbestos risk evaluation, EPA identified the conditions of use of asbestos, including imported raw bulk chrysotile asbestos for the fabrication of diaphragms for use in chlorine and sodium hydroxide production; several imported chrysotile asbestos-containing materials, including sheet gaskets for production of titanium dioxide; brake blocks for oil drilling, aftermarket automotive brakes/linings, and other vehicle friction products; other gaskets and packing; cement products; and woven products (Ref. 3). In identifying the conditions of use for asbestos and the rest of the first 10 chemicals undergoing risk evaluation under amended TSCA, EPA included use information reported under the CDR rule. In addition to using CDR data to identify the current conditions of use of asbestos, EPA conducted extensive research and outreach. This included EPA's review of published literature and online databases including Safety Data Sheets (SDSs), the United States Geological Survey's Mineral Commodities Summary and Minerals Yearbook, the U.S. International Trade Commission's Dataweb, and government and commercial trade databases. (See Docket EPA-HQ-OPPT-2016-0736). Additionally, EPA worked with its federal partners, such as Customs and Border Protection, to enhance its understanding of import information on asbestos-containing products in support of the risk evaluation.

EPA also reviewed company websites of potential manufacturers, importers, distributors, retailers, or other users of asbestos and received public comments (1) during the February 2017 public meeting on the scoping efforts for the risk evaluations for the first ten chemicals, (2) when EPA published the Scope of the Risk Evaluation for Asbestos in June 2017, and (3) when EPA published the Problem Formulation of the Risk Evaluation for Asbestos in June 2018, all of which were used to identify the conditions of use. (See Docket EPA-HQ-OPPT-2016-0736). In addition, to inform EPA's understanding of the universe of conditions of use for asbestos for the

scope document published in June 2017, EPA convened meetings with companies, industry groups, chemical users, and other stakeholders (Ref. 3). Lastly, on June 11, 2018, EPA proposed a significant new use rule (SNUR), in an administrative proposal separate and apart from the ongoing risk evaluation process under TSCA section 6, for certain uses of asbestos (including asbestos-containing goods) (83 FR 26922; FRL-9978-76) and asked for public comment or information on ongoing uses of asbestos. In the public comments submitted on the SNUR, EPA received no new information on any ongoing uses. (See Docket EPA-HQ-OPPT-2018-0159).

In the Problem Formulation for asbestos, based on the aforementioned outreach and research, EPA did not identify any conditions of use of asbestos as a byproduct or as an impurity. As stated in EPA's Problem Formulation for asbestos (Ref. 3), EPA has identified the conditions of use as imported raw bulk chrysotile asbestos for the fabrication of diaphragms for use in chlorine and sodium hydroxide production; several imported chrysotile asbestos-containing materials, including sheet gaskets for production of titanium dioxide; brake blocks for oil drilling, aftermarket automotive brakes, linings, and other vehicle friction products; other gaskets and packing; cement products; and woven products.

The purpose of EPA's risk evaluation is to determine whether a chemical substance presents an unreasonable risk to health or the environment, under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation (15 U.S.C. 2605(b)(4)(A)). As part of this process, EPA must evaluate both hazard and exposure, excluding consideration of costs or other non-risk factors, use scientific information and approaches in a manner that is consistent with the requirements in TSCA for the best available science, and ensure decisions are based on the weight-of-scientific-evidence. EPA intends to finalize the risk evaluation for asbestos by December 2019, as required by TSCA.

ii. The CDR rule. The CDR rule requires U.S. manufacturers (including importers) of chemicals on the TSCA Inventory, with some exceptions, to report to EPA every four years the identity of chemical substances manufactured (including imported) for all years since the last principal reporting year (40 CFR 711.8(a)(2)). For example, for the 2020 submission period, the principal reporting year will be 2019; the principal reporting year for the 2016 submission period was 2015. Per the CDR rule at 40 CFR 711.20, the 2020 submission period will be from June 1, 2020, to September 30, 2020, followed by EPA review and validation of the reported data before it is released to the public. Reporting during the 2020 submission period will cover the manufacture of chemicals in 2016, 2017, 2018, and 2019. To reduce reporting burden, detailed information is required only for the principal reporting year (i.e., 2019), including a breakout of the production volume to provide separate volumes for domestically manufactured and imported amounts. Generally, reporting is required for substances with production volumes of 25,000 pounds or more at any single site during any of the calendar years since the last principal reporting year. However, a lower threshold applies for chemical substances that are the subject of certain TSCA actions (see 40 CFR 711.8(b)). The CDR regulation generally exempts several groups of chemical substances from its reporting requirements, e.g., polymers, microorganisms, naturally occurring chemical substances, certain forms of natural gas, and water (see 40 CFR 711.5 and 711.6).

iii. Exemptions from reporting under the CDR rule. In addition to the exemption for naturally occurring chemical substances, if the chemical substance is imported solely as part of an article, the chemical substance is exempt from being reported under the CDR rule (40 CFR 711.10(b)). An article is defined in 40 CFR 704.3 as "a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end-use function(s) dependent in

whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design."

Under the CDR rule, a byproduct may be reportable when it is manufactured for a commercial purpose. The definition of manufacture for commercial purposes at 40 CFR 704.3 includes: "...substances that are produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture, including both byproducts..." Under 40 CFR 720.30(g) a byproduct is exempt from reporting if: "...its only commercial purpose is for use by public or private organizations that (1) burn it as a fuel, (2) dispose of it as a waste, including in a landfill or for enriching soil, or (3) extract component chemical substances from it for commercial purposes. (This exclusion only applies to the byproduct; it does not apply to the component substances extracted from the byproduct.)"

Impurities are exempt from CDR requirements. See 40 CFR 711.10(c) and 40 CFR 720.30(h)(1). An impurity is defined as a chemical substance unintentionally present with another chemical substance (40 CFR 704.3). Impurities are not manufactured for distribution in commerce as chemical substances per se and have no commercial purpose separate from the substance, mixture, or article of which they are a part.

Furthermore, processors do not report under the CDR rule. Processing information is reported by the manufacturers: if a manufacturer reports a chemical under the CDR rule, it must also report processing and use information for the chemical substance unless it is exempted from this reporting by 40 CFR 711.6(b).

iv. Asbestos reporting under the CDR rule. Two companies, both from the chlor-alkali industry, reported importing raw asbestos during the 2016 CDR reporting cycle (Ref. 4) and did not claim the exemption for naturally occurring substances. Both companies claimed their reports as CBI. Because asbestos has not been mined or otherwise produced in the United States since 2002 (Ref. 5), all raw asbestos used in the U.S. is imported.

V. Petition Response

A. What was EPA's response?

After careful consideration, EPA has denied the petition. A copy of the Agency's response, which consists of a letter to the signatory petitioner from the Asbestos Disease Awareness Organization (Ref. 6), is available in the docket for this TSCA section 21 petition. In accordance with TSCA section 21, the reasons for the denial are set forth in this **Federal Register** document.

B. What are the details of the petitioners' requests and EPA's decision to deny each of the requests?

This unit provides the reasons for EPA's decision to deny the petition asking EPA to amend the CDR rule and lift CBI protection for asbestos for all reports under the CDR rule.

i. Require immediate reporting of asbestos to CDR for the 2016 reporting cycle. a. Petitioners' request. The petitioners requested revisions to the CDR rule that would "trigger immediate reporting on asbestos for the 2012-2016 reporting cycle." To do this, the petitioners requested that EPA amend 40 CFR 711.20 to read: "For asbestos, the 2016 CDR submission period is from January 1, 2019 to April [30], 2019" (Ref. 1). The petitioners believe that this information will be useful to EPA in support of the ongoing asbestos risk evaluation, which is required to be completed by December 22, 2019, and any subsequent risk management

rulemakings under TSCA section 6(a).

More specifically, the request for immediate reporting was made by the petitioners to "make it possible for EPA to review and analyze the reports submitted while the risk evaluation is underway and to revise the draft evaluation on the basis of new information reported on asbestos importation and use" (Ref. 1). Additionally, the petitioners suggested that EPA "extend the completion date for the asbestos risk evaluation by six months under section 6(b)(4)(G)(ii)" to allow the Agency time to receive the new data collected under the CDR rule as proposed (Ref. 1).

b. Agency response. EPA does not believe that the requested amendments would result in the reporting of any information that is not already known to EPA. As noted in more detail in Unit IV, EPA conducted extensive research and outreach to develop its understanding of import information on asbestos-containing products in support of the ongoing asbestos risk evaluation. After more than a year of research and stakeholder outreach, EPA believes that the Agency is aware of all ongoing uses of asbestos and already has the information that EPA would receive if EPA were to amend the CDR requirements. As such, amending the CDR requirements would not provide the Agency with any additional information, and EPA does not believe it would collect information on any new ongoing uses by making the requested amendments to the CDR rule.

Furthermore, even if EPA believed that the requested amendments would collect information on any new ongoing uses, EPA would not be able to finalize such amendments in time to inform the ongoing risk evaluation or, if needed, any subsequent risk management decision(s). The petitioners stated that their requested revisions should "trigger immediate reporting on asbestos for the 2012-2016 reporting cycle" (Ref. 1). Specifically, the petitioners asked that EPA amend 40 CFR 711.20 to require reporting for the 2016 CDR submission period

(i.e., 2012-2015); they requested that this reporting be required to start on January 1, 2019, and to end on April 30, 2019.

The petitioners, however, submitted their request on September 27, 2018, less than 120 calendar days before they would like the submission period to begin. While EPA understands that petitioners desire prompt collection of the requested information under the CDR rule to inform the ongoing risk evaluation, this request does not factor in the necessary timeframes for any rulemaking processes that would be required to propose and then finalize such amendments. To allow for the notice and comment period for the public and regulated community required under the Administrative Procedure Act (5 U.S.C. 553) and for appropriate internal deliberation prior to proposal and after the close of the comment period, EPA typically needs at least 18 months to finalize a rulemaking. Furthermore, even if EPA were able to use expedited rulemaking procedures to quickly promulgate a requirement to report additional information on asbestos for the 2016 CDR cycle, it is important to note that potential reporters have had no prior notice or expectation of a need to retain the records necessary to report on past chemical manufacturing. Therefore, EPA has no reason to expect that potential reporters subject to such a rule amendment would have information that could be reasonably ascertainable for submission.

Additionally, the January through April 2019 submission period that the petitioners requested would not, in fact, provide timely information for the ongoing risk evaluation on asbestos. While the petitioners suggest that EPA "should extend the completion date for the asbestos risk evaluation by six months under section 6(b)(4)(G)(ii)" (Ref. 1), such an extension would not allow time for EPA to (1) conduct a data collection effort under the CDR rule and (2) incorporate this data into the ongoing risk evaluation prior to public comment and peer review.

Petitioners' request to extend the completion date of the final risk evaluation for asbestos

by six months would move the completion from December 2019 to June 2020. Yet, any changes to the CDR rule would need to be made by notice-and-comment rulemaking that would involve, at a minimum, five to eight months to develop the proposed rule, a 30 to 60-day comment period, and five to eight months to complete the final rule. Under this hypothetical rulemaking scenario outlined, even if the rulemaking process began in December 2018, the data elements requested by the petitioners would not result in available data until, at the very earliest, March 2020 (only three months prior to completion of the six-month deferred risk evaluation). Petitioners' request ignores the fact that the draft risk evaluation must undergo public comment and peer review, which is a four to eight-month process (see 15 U.S.C. 2605(b)(4)(H); 40 CFR 702.45; 40 CFR 702.49).

Moreover, even if the regulations were amended and, in response to the finalized amendments, chemical manufacturers could reasonably ascertain and provide the newly-required information, EPA would be receiving information on manufacturing, import, and processing for conditions of use that may no longer be ongoing conditions of use. Rather, this type of information would concern recently ceased or legacy use **Ex. 5 Deliberative Process (DP)**

Ex. 5 Deliberative Process (DP) As an example, in comparing the 2012 and 2016 United

States Geological Survey Minerals Yearbook for asbestos (Refs. 7 and 5), EPA has observed that a number of importers of raw asbestos and asbestos-containing articles are exiting or have already exited the market. As a result, all or a significant part of the information they would report for activities undertaken during the 2016 CDR submission period (i.e. 2012-2015) would likely consist of conditions of use that are no longer ongoing, and, thus, uninformative for the risk evaluation.

In sum, EPA believes - based on the extensive research and data gathering already

Ex. 5 Deliberative Process (DP)

conducted during the asbestos risk evaluation process – that the requested amendments to the CDR rule would not lead to the reporting of new information that would contribute to EPA's ongoing asbestos risk evaluation or, if needed, subsequent risk management decision(s). Based on outreach and research, EPA believes that the Agency already has the information that would be collected, without amending the CDR rule. Furthermore, and, as previously discussed, EPA would not be able to promulgate a rulemaking to require the reporting by the submission period (beginning January 1, 2019) the petitioners requested, nor would the rulemaking amendments discussed above allow EPA to receive any new information in time to inform the ongoing asbestos risk evaluation.

EPA finds that petitioners have not set forth sufficient facts to establish that it is necessary to issue the requested amendment to require immediate past reporting of the manufacturing and use of asbestos under the CDR rule for the 2016 reporting cycle.

ii. Lift exemption for naturally occurring chemical substances for asbestos. a.

Petitioners' request. Several times in the petition, the petitioners requested that EPA either add asbestos to the CDR rule or close what they referred to as a "reporting loophole" for asbestos under the CDR rule. Under the exemption for naturally occurring chemical substances at 40 CFR 711.6(a)(3), manufacturers (including importers) do not have to report a chemical substance when the substance is manufactured as described at 40 CFR 710.4(b).

As support for the petitioners' claim of a reporting loophole for asbestos, the petitioners cited EPA's letter to Occidental Chemical Corporation (Occidental), dated July 28, 2017, wherein EPA stated that it did not believe Occidental was required to report its imports of asbestos under the CDR rule because Occidental's operations satisfied the criteria of the naturally occurring chemical substances exemption (Ref. 1). EPA issued this letter in response to

the Asbestos Disease Awareness Organization's notice of intent to sue Occidental for what the Organization believed to be a CDR violation. In reaction to EPA's letter to Occidental, the petitioners stated that "EPA's interpretation of the CDR rule means that no manufacturers or importers of asbestos or asbestos-containing products were required to report on their activities" (Ref. 1). The petitioners further posited that "this loophole in the rule has resulted in a troubling – and wholly avoidable – lack of reliable information about who is importing asbestos and in what quantities, where and how asbestos is being used in the U.S., and who is being exposed and how that exposure is occurring" (Ref. 1).

b. Agency response. EPA emphasizes that manufacturers and importers of asbestos are already required to report asbestos under the CDR rule if they meet the production volume threshold of 2,500 pounds and do not qualify for an exemption (including the naturally occurring substances exemption). As noted above, during the last reporting cycle, two companies reported under the CDR rule the import of asbestos for use in the chloro-alkali industry to make asbestos diaphragms. After extensive research and outreach, including with Customs and Border Protection, EPA believes that the chloroalkali industry is the only importer of raw bulk asbestos, and the Agency has sufficient volume, import, use, and hazard data from the industry to conduct the risk evaluation.

Ex. 5 Deliberative Process (DP) to believe that *no* domestically manufactured or imported asbestos is currently required to be reported under the CDR rule as a result of the exemption for naturally occurring substances. EPA's letter to Occidental, however, found that the exemption for naturally occurring substances applied under the specific circumstances described in the letter. EPA did not find that the exemption applied for all "manufacturers or importers of asbestos or asbestos-containing products" as claimed by petitioners.

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In general, the petitioners, misunderstand the naturally occurring substances exemption's specific definition. As defined by 40 CFR 711.6(a)(3), a naturally occurring chemical substance is:

Any naturally occurring chemical substance, as described in 40 CFR 710.4(b). The applicability of this exclusion is determined in each case by the specific activities of the person who manufactures the chemical substance in question. Some chemical substances can be manufactured both as described in 40 CFR 710.4(b) and by means other than those described in 40 CFR 710.4(b). If a person described in § 711.8 manufactures a chemical substance by means other than those described in 40 CFR 710.4(b), the person must report regardless of whether the chemical substance also could have been produced as described in 40 CFR 710.4(b). Any chemical substance that is produced from such a naturally occurring chemical substance described in 40 CFR 710.4(b) is reportable unless otherwise excluded.

A chemical substance qualifies as naturally occurring only if it is: (1)(i) unprocessed or (ii) processed only by manual, mechanical, or gravitational means; by dissolution in water; by flotation; or by heating solely to remove water; or (2) extracted from air by any means (40 CFR 710.4(b)). Mined materials such as metal ores, minerals, and clays that are separated from the natural environment by only physical means are examples of chemical substances that are considered naturally occurring for TSCA purposes and are exempt from reporting under the CDR rule. If this specifically defined exemption does not apply (and if no other exemption applies), then a manufacturer or importer of asbestos must report under the CDR rule. In addition, given that the purpose of domestic manufacturing or importing of raw asbestos is to make asbestos diaphragms, for which EPA already has use and exposure information, removing the exemption for reporting on naturally occurring substances for asbestos would not provide any additional data to EPA. EPA already has this information obtained through extensive outreach and research (as described in Unit IV.A.i.).

EPA finds that petitioners have not set forth sufficient facts to establish that it is

necessary to issue the requested amendment to lift the naturally occurring chemical substances exemption for asbestos under the CDR rule.

iii. Require reporting of imported articles containing asbestos. a. Petitioners' request. As noted by the petitioners, 40 CFR 711.10(b) exempts from reporting persons who import a reportable substance as part of an article. Additionally, the petitioners asserted that "since a large number of the asbestos-containing products historically in use are articles, this exemption would prevent EPA from obtaining a considerable amount of useful information about asbestos use and exposure in the U.S." As such, the petitioners requested that EPA make the articles exemption at 40 CFR 711.10 inapplicable to asbestos. Furthermore, they requested that reporting be required for "all imported articles in which asbestos is present at detectable levels" (Ref. 1).

b. Agency response. Import of a chemical substance as part of an article is not subject to reporting under the CDR rule (40 CFR 711.10(b)). A chemical substance is considered to be imported "as part of an article" if the substance is not intended to be removed from that article and has no end use or commercial purpose separate from the article of which it is a part (Ref. 8).

While the petitioners correctly pointed out that "a large number of the asbestoscontaining products historically in use [were] articles" (Ref. 1), these uses, along with most uses of asbestos, have ceased and thus are not being evaluated as part of the ongoing asbestos risk evaluation **Ex. 5 Deliberative Process (DP)** (Ref. 3). As identified in the

Problem Formulation of the Risk Evaluation for Asbestos, currently imported articles include asbestos-containing sheet gaskets, other gaskets and packing, aftermarket automotive brakes/linings, other vehicle friction products, brake blocks, asbestos cement products, and woven products. EPA has relied on extensive outreach and research, including sources other than the CDR rule, to determine the conditions of use of asbestos, as described in Unit IV.A.i. The

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Agency does not believe amending the CDR rule would be helpful in collecting additional import information on articles. EPA has sufficient information on imported articles containing asbestos to conduct the risk evaluation and inform subsequent risk management decisions based the risk determination.

Though the petitioners suggested that there may be import of additional articles containing asbestos that EPA is unaware of, they provide no examples of any such known or ongoing imports of asbestos articles and provide no reason to believe that there may be any of which EPA is unaware. Considering the extensive outreach and research that has been conducted since December 2016, EPA has no reason to believe there are ongoing imports of articles containing asbestos that are unknown to EPA.

While the petitioners requested that EPA require reporting for "all imported articles in which asbestos is present at detectable levels" (Ref. 1), the information that manufacturers are required to report under the CDR rule is limited to information "known to or reasonably ascertainable" by the reporter (40 CFR 704.3). EPA could not require manufacturers to test these products for the purposes of CDR reporting under TSCA section 8. Therefore, EPA would not be able to require CDR reporters to report articles in which the potential presence of asbestos could be determined only through testing.

Additionally, because information reported under the CDR rule is limited to that which is "known to or reasonably ascertainable" by the reporter, even if EPA were to require the reporting of asbestos-containing articles under the CDR rule, importers would rely on information readily available to them, such as Safety Data Sheets or other documentation provided by their foreign supplier. EPA does not believe that making the requested amendment to the CDR rule would result in importers reporting articles that are not already known to EPA because the Agency has

conducted its own research to analyze Safety Data Sheets and other evidence in order to determine the conditions of use of asbestos for the risk evaluation. EPA believes that lifting the articles exemption for the reporting of asbestos under the CDR rule would not provide any new use information that would inform the ongoing risk evaluation or any subsequent risk management decisions, if needed.

For these reasons, EPA believes that the petitioners have failed to set forth sufficient facts to establish that it is necessary to issue the requested amendment to lift the articles exemption for asbestos under the CDR rule.

iv. Lift the byproduct and impurity exemption for asbestos. a. Petitioners' request. The petitioners cited 40 CFR 711.10(c), which exempts from CDR reporting activities described in 40 CFR 720.30(g) and (h). Under this exemption, manufacturers (including importers) do not have to report a chemical substance when the substance is an impurity or a byproduct not used for commercial purposes. The petitioners requested that these exemptions be made inapplicable to asbestos, "since the low levels of asbestos that have been found in makeup and crayons may be unintended contaminants that comprise byproducts and impurities" (Ref. 1). Moreover, the petitioners stated that, "EPA needs information about asbestos-contaminated consumer products to conduct a complete and protective risk evaluation" (Ref. 1)

b. Agency response. Under 40 CFR 720.30(g), a byproduct is exempt from reporting if:
"...its only commercial purpose is for use by public or private organizations that (1) burn it as a
fuel, (2) dispose of it as a waste, including in a landfill or for enriching soil, or (3) extract
component chemical substances from it for commercial purposes." Under 40 CFR 720.30(h), any
(1) impurity or (2) any byproduct that is not used for a commercial purpose is not subject to
reporting. Based on the extensive outreach and research undertaken by EPA in connection with

developing the ongoing asbestos risk evaluation, EPA is unaware of any examples of asbestos as a byproduct. Thus, EPA anticipates there would be no new information reported if the Agency were to lift the byproduct exemption for asbestos.

With regard to the impurity exemption, the petitioners requested that these exemptions be made inapplicable to asbestos "since the low levels of asbestos that have been found in makeup and crayons *may be* unintended contaminants that comprise byproducts and impurities" (emphasis added). However, these findings were made only after independent laboratory testing of final consumer products, and petitioners make no attempt to explain why they believe these findings are the result of the *manufacture* of asbestos as a byproduct or impurity such that it would be reportable under the CDR rule if the Agency required such reporting. Indeed, the CDR rule does not require submitters to perform chemical analyses of products containing the chemicals they manufacture. Instead, the information required when reporting on a chemical is limited to information that is "known to or reasonably ascertainable" by the manufacturer. This standard is applicable to all information reported in accordance with 40 CFR 711.15(b) as required by TSCA section 8(a)(2). Thus, it is unlikely that EPA would receive new information that would change its understanding of the conditions of use for asbestos that can be addressed under TSCA.

EPA does not believe that making the requested amendment to the CDR rule would result in reporting of asbestos as an impurity or a byproduct, for uses that are known or reasonably ascertainable, and the petitioners have not provided evidence that there are such known uses that are ongoing but remain outside the scope of the asbestos risk evaluation. EPA finds that the petitioners have failed to set forth sufficient facts to establish that it is necessary to issue the requested amendment to lift the byproducts and impurities exemptions for asbestos under the

CDR rule.

v. Lower asbestos reporting threshold to 10 pounds. a. Petitioners' request.

Manufacturers (including importers) are required to report under the CDR rule if they meet certain production volume thresholds, generally 25,000 pounds or more of a chemical substance at any single site. However, a reduced reporting threshold of 2,500 pounds applies to chemical substances subject to certain TSCA actions (40 CFR 711.8). The petitioners correctly point out that because asbestos is subject to a TSCA section 6 action (40 CFR 763, Subpart I), it is subject to the lower reporting threshold of 2,500 pounds. The petitioners believe that even the reduced reporting threshold "is too high in view of the absence of any safe level of exposure to asbestos and the need for comprehensive use and exposure information for the ongoing risk evaluation" (Ref. 1). The petitioners therefore request that the reporting threshold for asbestos be lowered to 10 pounds for any year in the CDR reporting period.

b. Agency response. Since asbestos is no longer mined in the United States and the only importation of raw asbestos is for production of asbestos diaphragms, for which yearly imports for each site well exceed the threshold of 2,500 pounds, lowering the reporting threshold would not provide additional information to EPA. As a result, EPA believes that it already sufficient import data from the chloralkali industry to support conducting the risk evaluation.

While the petitioners believe that the current reporting threshold "is too high in view of the absence of any safe level of exposure to asbestos and the need for comprehensive use and exposure information for the ongoing risk evaluation," they fail to show that lowering the reporting threshold would provide any new information to EPA. Therefore, EPA finds that the petitioners have failed to set sufficient facts to establish that it is necessary to issue the requested amendment to lower the CDR reporting threshold for asbestos.

vi. Add processors of asbestos to CDR. a. Petitioners' request. The petitioners pointed out that, while EPA has the authority to require that processors report under the CDR rule, processors are not currently subject to CDR reporting requirements. The petitioners requested that EPA amend the CDR rule to require reporting from asbestos processors asserting that, while manufacturers (including importers) of a chemical substance are required to report downstream processing and use information under the CDR rule, "in many cases, importers will be unable to provide the detailed information about use and exposure necessary for full understanding of the risks posed by these products. Therefore, the additional information available to processors will be essential" (Ref. 1).

b. Agency response. Currently, the CDR rule does not require processors of any chemical substances to report. However, EPA knows of only two ongoing uses of asbestos that constitute processing: (1) the processing of raw asbestos into diaphragms and (2) the fabrication of gaskets from imported asbestos-containing sheet gaskets. Information on these uses is well understood by EPA as a result of direct communication with these processors (see Problem Formulation for asbestos (Ref. 3)). Accordingly, EPA does not believe that requiring processors of asbestos under the CDR rule will provide useful information not already in the Agency's possession. The petitioners have failed to indicate what additional information EPA would collect by requiring asbestos processors to report under the CDR rule. Therefore, EPA finds that the petitioners have failed to set forth sufficient facts to establish that it is necessary to issue the requested amendment to require processors of asbestos to report under the CDR rule.

vii. Lift CBI claims for all reports to CDR for asbestos. a. Petitioners' request. In addition to the requests made under TSCA section 8, the petitioners requested that EPA use its authority under TSCA sections 14(d)(3) and 14(d)(7) to lift CBI claims on asbestos information

reported under the CDR rule.

TSCA section 14(d)(3) states that CBI "shall be disclosed if the Administrator determines that disclosure is necessary to protect health or the environment against an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use" (15 U.S.C. 2613(d)(3)). The petitioners requested that EPA use its authority under TSCA section 14(d)(3) to lift CBI claims on information reported under the CDR rule, "given the significant risk of harm that asbestos presents at any level of exposure, knowledge of how, where and in what quantities asbestos and asbestos-containing products are being imported and used is clearly necessary to protect against unreasonable risks and EPA would have an ample basis to make a determination to that effect" (Ref. 1).

TSCA section 14(d)(7) states that CBI "may be disclosed if the Administrator determines that disclosure is relevant in a proceeding under this Act, subject to the condition that the disclosure is made in such a manner as to preserve confidentiality to the extent practicable without impairing the proceeding" (15 U.S.C. 2613(d)(7)). For EPA's authority under TSCA section 14(d)(7), the petitioners posited that "the ongoing asbestos risk evaluation is such a 'proceeding' and information on asbestos importation and use is clearly 'relevant' because it has a direct bearing on EPA's determinations of exposure and risk and the ability of the public to comment on these elements of the risk evaluation" (Ref. 1).

b. Agency response. Petitioners' request is not appropriate for a TSCA section 21 petition. Under TSCA section 21 (15 U.S.C. 2620(a)), any person can petition EPA to initiate a rulemaking proceeding for the issuance, amendment, or repeal of a rule under TSCA sections 4,

6, or 8, or an order under TSCA sections 4 or 5(e) or (f). Under this express statutory language, therefore, a TSCA section 21 petition is not a vehicle to petition EPA to initiate an action under TSCA section 14.

Moreover, even if petitioners could use the TSCA section 21 mechanism to request an action under TSCA section 14, the petitioners have not made a sufficient case for lifting CBI protections as described by either TSCA section 14(d)(3) or section 14(d)(7). TSCA section 14(d)(3) states that CBI "shall be disclosed if the Administrator determines that disclosure is necessary to protect health or the environment against an unreasonable risk of injury to health or the environment...." The asbestos risk evaluation is ongoing for the uses reported under the CDR rule, and EPA has yet to determine if these uses pose an unreasonable risk. In the absence of an unreasonable risk finding for a condition of use, EPA cannot make a determination whether disclosure is necessary under TSCA section 14(d)(3). TSCA section 14(d)(7) states that CBI "may be disclosed if the Administrator determines that disclosure is relevant in a proceeding under this Act, subject to the condition that the disclosure is made in such a manner as to preserve confidentiality to the extent practicable without impairing the proceeding." However, EPA believes that disclosure of CBI would have no practical relevance to the risk evaluation or risk determination as the CBI claims are limited and EPA retains the ability to characterize the information without revealing the actual protected data. Accordingly, EPA denies this request.

V. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating

these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

- Asbestos Disease Awareness Organization, American Public Health Association,
 Center for Environmental Health, Environmental Working Group, Environmental Health
 Strategy Center, and Safer Chemicals Healthy Families to Andrew Wheeler, Acting
 Administrator, Environmental Protection Agency. Re: Petition under TSCA Section 21 to
 Require Reporting on Asbestos Manufacture, Importation and Use under TSCA Section 8(a).
 Received September 27, 2018.
- Bob Sussman email to Jeff Morris, Director of EPA's Office of Pollution Prevention and Toxics. RE: TSCA Section 21 Petition. Received November 29, 2018.
- 3. EPA. Problem Formulation of the Risk Evaluation for Asbestos. May 2018.

 Washington, DC: US Environmental Protection Agency, Office of Pollution Prevention and Toxics. [HYPERLINK "https://www.epa.gov/sites/production/files/2018-06/documents/asbestos_problem_formulation_05-31-18.pdf"].
- 4. EPA. Public database 2016 chemical data reporting (May 2017 release). Washington, DC: US Environmental Protection Agency, Office of Pollution Prevention and Toxics. Retrieved from [HYPERLINK "https://www.epa.gov/chemical-data-reporting"].
- Flanagan, DM. (2016). 2015 Minerals yearbook. Asbestos [advance release]. In US Geological Survey 2015 Minerals Yearbook. Reston, VA: U.S. Geological Survey. [
 HYPERLINK "https://minerals.usgs.gov/minerals/pubs/commodity/asbestos/myb1-2015-asbes.pdf"].
- EPA. Response to Petition to Require Reporting on Asbestos Manufacture,
 Importation and Use under TSCA Section 8(a). Letter. 2018.

- 7. Virta, Robert. (2012). 2012 Minerals yearbook. Asbestos. In US Geological Survey 2015 Minerals Yearbook. Reston, VA: U.S. Geological Survey. [HYPERLINK "https://minerals.usgs.gov/minerals/pubs/commodity/asbestos/myb1-2012-asbes.pdf"].
 - 8. EPA. TSCA Chemical Data Reporting. Fact Sheet: Articles. August 3, 2012. [

HYPERLINK

 $"https://www.epa.gov/sites/production/files/documents/articles factsheet forcdr_reporting_080312 \\ .pdf" \].$

List of Subjects in 40 CFR Chapter I

Environmental protection, Asbestos, Flame retardants, Chemicals, Confidential
business information, Hazardous substances, Reporting and recordkeeping requirements.
Dated:
Nancy B. Beck, Ph.D.

Principal Deputy Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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